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Nixon & Vanderhye P.C.

NOV 3 0 2006

11TH FLOOR 901 NORTH GLEBE ROAD ARLINGTON, VIRGINIA 22203 TELEPHONE: (703) 816-4000 FACSIMILE: (703) 816-4100 WRITER'S DIRECT DIAL NUMBER: (703) 816-4091

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	Dur Ref.:	2551-114					
	our Ref.:	Appin No. 09/638,693	Date:	November 30, 2006			
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CONFIDENTIALITY NOTE The documents accompanying this facsimile transmission contain information belonging to Nixon & Vanderhye, which is confidential and/or legally privileged. This information is only intended for the use of the individual or entity named above. IF YOU ARE NOT THE NAMED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION OR TAKING OF THIS INFORMATION FOR ANY USE WHATSOEVER IS STRICTLY PROHIBITED. If you have received this facsimile in error, please immediately contect us by telephone to arrange for return of the original documents to us.

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MAERTENS et al.		C/A.U.		-11	(3) PTO Memo of June 1, 2005 re Acceptance of Certain Non-Comp	o: pliant	
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Title: NEW SEQUEN	CES OF HEPATITIS C VI	RUS GENOT	YPES AN	ND THEIR USE AS	2000; (5) copy of pages 93 and 94 of o	rigine)	ly-filed
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firm) to our Accoun	No. 14-1140. A duplic	ate copy of t	his shee	it is attached.			
				VANDERHYE P.	.C.		
901 North Glebe R Arlington, Virginia	oad, 11th ridor 2203-1808		By Atty:	B. J. Sadoff, Reg.	No. 36,663		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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NOV 3 0 2006

In re Patent Application of

MAERTENS et al.

Atty. Ref.: 2551-114; Confirmation No. 2821

Appl. No. 09/638,693

TC/A.U. 1634

Filed: August 15, 2000

Examiner: Martinell

For: NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS

THERAPEUTIC AND DIAGNOSTIC AGENTS

November 30, 2006

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR PATENT TERM ADJUSTMENT PURSUANT TO 37 CFR § 1.705(b)

The Office is requested to reconsider the Patent Term Adjustment (PTA) of the above-identified application.

Specifically, the Determination of Patent Term adjustment under 35 U.S.C. 154(b) dated August 30, 2006 states that the Patent Term Adjustment to date is 0 days.

A copy of the Patent Term Adjustment History calculation printed from the Patent Office IFW (hereinafter referred to as "PTO IFW") is attached. As some of the dates in the PTO PTA calculation appear to be missing or incorrect, the following provides what the applicants believe to be some relevant facts.

The present Application is being filed on the same day the issue fee is being paid.

200.00 DP

PAGE 6/24 * RCVD AT 11/30/2006 7:58:07 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-210 * DNIS:27:38:300 * CSID:703 816 4100 * DURATION (mm-55):06-40 MAERTENS et al. Appl. No. 09/638,693 November 30, 2006

The fee set forth in 37 CFR § 1.18(e) (fee code 1455, \$200) is attached in the form of a Credit Card Payment Form.

The following is offered by way of background of the Patent Office extensive delay in the prosecution of the present application.

The application was filed August 18, 2000, with, among other things, 23 numbered claims (i.e., claims 1-23), a copy of the inventors' Declaration and a paper copy of a \$equence Listing and a Request that the computer readable copy of the Sequence Listing from the parent application Serial No. 08/362,455, be used for the present application.

On October 12, 2000 the Patent Office mailed a Notice to File Missing Parts requiring submission of the inventors' Declaration.

On November 14, 2000 the applicants filed a Response and Amendment noting the inventors' Declaration had been previously filed and supplying evidence of same and amending the claims to cancel claims 1-24 while adding new claims 24-55. See Remarks on page 18 of the Response and Amendment dated November 14, 2000 and attached DIPE date-stamped page 1 of the Response and Amendment retrieved from the PAIR IFW.

On March 1, 2001 the applicants filed a corrective paper indicating that claims 1-23 should have been indicated as having been canceled and new claims 24-55 were pending.

On May 17, 2001 a further Preliminary Amendment was filed canceling claims 24-55 and adding new claims 56-85.

On <u>December 17, 2001</u> the Patent Office mailed an Office Action requiring an election of undetermined scope and submission of a Sequence Listing. The Office Action indicated that claims "54-83" which the Examiner had renumbered pending claim 56-85 as the Examiner asserted only 21 numbered claims had been originally-filed.

This statement was in error. <u>See</u> attached copy of pages 93 and 94 (claims 22 and 23) of the originally-filed application from the PTO IFW which contain the PTO-printed Serial No. and filing date of the present application.

On <u>January 17, 2001</u> the applicants responded by electing a single sequence, with traverse, noting the Examiner's error with regard to the originally-filed claims.

On <u>March 25, 2002</u> the Office mailed a further Communication requiring a Sequence Listing and making incomplete assertions as to the originally-filed claims and specification.

On May 28, 2002 the applicants responded with an Amendment noting the earlier-filed Sequence Listing and requesting clarification with regard to the Examiner's comments on the content of the originally-filed papers.

On July 29, 2002 a further Communication was mailed wherein further objections were made regarding the originally-filed application and suggesting that it was the applicants burden to inspect the Patent Office copy of the file to demonstrate the contents of the originally-filed application - a chore made much less burdensome with the availability of the PTO IFW.

On August 7, 2002 the undersigned personally traveled to the Patent Office and met with the Examiner's Supervisor to address what may or may not be contained in the PTO file. It is the undersigned's memory that the Patent Office file contained a

PAGE 8124 * RCVD AT 113002006 7:58:07 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-210 * DNIS:2738300 * CSID:703 816 4100 * DURATION (mm-ss):06-40 MAEKIENS et al. Appl. No. 09/638,693

November 30, 2006

completely unrelated application, due to PTO error. Examiner Woodward confirmed same in the Interview Summary of August 7, 2002 which states as follows: "USPTO INSERTED WRONG SPECIFICATION IN CASE. CORRECT SPECIFICATION WILL BE INSERTED & AMENDMENTS PROCESSED. NO RESPONSE TO PAPER NO:17 (07/29/02) IS NECESSARY."

On March 24, 2003 an Office Action was mailed requiring an election of indeterminate scope and/or definition.

The Office Action of March 24, 2003 was the first Office Action to consider the pending claims. The period from the August 15, 2000 filing date to October 15, 2001 is 14 months. The period from October 16, 2001 through March 24, 2003 is a 525 day delay by the Patent Office to act on the case after the 14 months period from filing.

The period of Patent Office delay under 37 CFR § 1.702(a)(1) and § 1.703(a)(1) is believed therefore to be 525 days.

- Or June 24, 2003 an Amendment was filed in response to the Office Action of March 24, 2003, within three months of the mailing of the Office Action.
 - On September 11, 2003 a non-final Office Action was mailed.
- Оф December 11, 2003 an Amendment and Rule 181 Petition were filed in response to the Office Action of March 24, 2003, within three months of the mailing of the Office Action.
 - On <u>December 30, 2003</u> a Notice of Non-Compliant Amendment was mailed.
- On January 13, 2004 a response and new copy of the Amendment of December 11, 2003 was filed. The Patent Office appears to have calculated the period from

PAGE 9124 * RCVD AT 1130/2006 7:58:07 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-210 * DNIS:2738300 * CSID:703 816 4100 * DURATION (mm-ss):06-40 MALKIENS et al. Appl. No. 09/638,693 November 30, 2006

December 12, 2003 through January 13, 2004 (the number of days beginning on the day after the date that is three months after the date of the mailing or transmission of the Office communication ... and ending on the date the reply was filed (see 37 CFR § 1.704(b) and similarly 37 CFR § 1.704(c)(7))) as a 33 day delay however the applicants believe the period is only 32 days. Moreover, the applicants believe that the period should not be counted as a delay by the applicants as there appears to have been a great deal of discretion in the Patent Office as to whether a paper was non-compliant for indicating claims as "Previously Amended" (as in the applicants Amendment of December 11, 2003) as opposed to the "Previously Presented" of the Amendment submitted January 13, 2004. Evidence of such unequal treatment is provided by the attached Memo (*Acceptance of Certain Non-Compliant Amendments Under 37 CFR 1.121(c)") dated June 1, 2005 from Joseph J. Rolla wherein it is indicated that "Previously amended" is an acceptable alternative of "Previously Presented".

The applicants submit therefore that the period of 32 days from December 12, 2003 through January 13, 2004 was not a delay which would have been uniformly considered by the Patent Office to have produced a reduction of the period of adjustment of Patent Term under 37 CFR § 1.704(b).

Or June 3, 2004 a final rejection was mailed. The period from December 12, 2003 through April 12, 2004 is a 4 month period prescribed by 37 CFR § 1.702(a)(2). Alternative, the period from January 14, 2003 through May 14, 2003, is a 4 month period prescribed by 37 CFR § 1.702(a)(2). The Patent Office delay according to 37 CFR §1.703(a)(2) is either 53 days in the former or 21 days in the later. As the

PAGE 10124 * RCVD AT 1130/2006 7:55:07 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-210 * DNIS-2738300 * CSID:703 816 4100 * DURATION (mm-ss):06-40 Appl. No. 09/638,693

November 30, 2006

applicants believe the period from December 12, 2003 through January 13, 2004 should not be considered a delay for the purposes of calculating the PTA, the applicants believe the Patent Office's mailing of the Office Action of June 3, 2004 amounts to a further delay of 53 days pursuant to 37 CFR § 1.703(a)(2). Alternatively, the mailing of the Office Action constitutes a 21 day delay pursuant to 37 CFR § 1.703(a)(2).

On August 27, 2004 an Amendment Under Rule 116 was filed in response to the Office Action of June 3, 2004.

On October 13, 2004 an Advisory Action was mailed.

On December 3, 2004 a Notice of Appeal was filed to maintain pendency.

The period from September 4, 2004 through the December 3, 2004 filing of the Notice of Appeal is 91 days counted by the PTO as a delay in prosecution, presumably pursuant to 37 CFR § 1.704(b) however clarification is requested.

On February 1, 2005 a RCE and Amendment were filed.

Oφ November 17, 2005, a copy of the RCE and the undersigned's post card receipt were forwarded to the Examiner as requested by the Examiner in a teleconference. A copy of the submission from the PTO IFW is attached. The PTO PTA chronology appears to indicate that the RCE was filed November 17, 2005 when in fact it was filed February 1, 2005.

On <u>December 1, 2005</u> a personal interview was held with the Examiners.

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On <u>December 19, 2005</u> copies of previously-filed papers and post card receipts were filed in response to the Examiner's request for same.

The attached PTO PTA calculation includes a 32 day calculation for an alleged applicants delay from the alleged November 17, 2005 filling of the RCE through the January 4, 2006 date the RCE or some other unspecified paper was forwarded to the Examiner. Clarification is requested as to the basis in the Rules for this calculated alleged delay on the applicants part. From the time of the filling of the RCE on February 1, 2005, as throughout the entire prosecution of the present application, the applicants have been diligent in prosecution. This is especially true for the period from November 17, 2005 through allowance, which involved extensive travel and preparation for an interview with the Examiners. Clarification as to the basis of the alleged delay from November 17, 2005 through January 4, 2006 is requested in the event the Patent Office maintains that this period constitutes a period of delay by the applicants.

On March 2, 2006 an Office Action was mailed. The period from June 2, 2005 (i.e., the day after four months from the filing of the Amendment on February 1, 2005) through the mailing of the Office Action on March 2, 2006 is a period of 274 days which is submitted to constitute a delay by the Patent Office pursuant to 37 CFR § 703(a)(2).

On <u>June 2, 2006</u> an Amendment in response to the Office Action of March 2, 2006 was filed, within three months of the mailing of the Office Action.

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On August 30, 2006 a Notice of Allowance was mailed.

The above is believed to constitute a statement of facts required by 37 CFR § 1.705 (b)(2).

In summarizing (in the manner indicated in 37 CFR § 1.705(b)(2)), the applicants submit the following:

- (i) the correct Patent Term Adjustment is <u>761 days</u> (i.e., 525 + 53 + 274 0 -91);
- (ii) the relevant dates are specified above;
- (iii) the Patent is not subject to a Terminal Disclaimer; and
- (iv) the circumstances indicated in subparagraph (A) of this section are described above.

As detailed above, the total period of reduction of the period of adjustment of patent term, pursuant to 37 CFR § 1.705, is believed to be 761 days.

A Notice recalculating the PTA as requested above, or further explanation, is requested.

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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
B. J. Sadoff
Reg. No. 36,663

BJS: 901 North Glebe Road, 11th Floor Arlington, VA 22203-1808 Telephone: (703) 816-4000 Facsimile: (703) 816-4100

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Patent Term	Adjustments		00/520 503		
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08-27-2004	Workflow Incoming amendment IFW	21	-
06-03-2004	Mail Final Rejection (PTOL - 326)	21	
06-01-2004	Final Rejection	*	
05-24-2004	Petition Decision - Denied	÷	
12-11-2003	Petition Entered	• •	
01-28-2004	petition fee paid	*	
01-28-2004	Date Forwarded to Examiner	•	33
01-13-2004	Response after Non-Final Action		1
12-30-2003	Mail Notice of Informal or Non-Responsive Amendment		•
12-30-2003	Date Forwarded to Examiner		-
12-11-2003	Informal or Non-Responsive Amendment after Examiner Action		₽
12-11-2003	Response after Non-Final Action		_
09-11-2003	Mail Non-Final Rejection		
09-08 - 2003	Non-Final Rejection		
08-25-2003	CRF Is Good Technically / Entered into Database		
07-01-2003	Date Forwarded to Examiner		
06-24 - 2003	Response to Election / Restriction Filed		•
06-24-2003	Request for Extension of Time - Granted	70	
03-24-2003	Mail Restriction Requirement	70	
03-23-2003	Requirement for Restriction / Election	↑	
01-22-2003	Date Forwarded to Examiner	T	
09-13-2002	Response after Non-Final Action	T	
08-07-2002	Examiner Interview Summary Record (PTOL - 413)		
07-29 - 2002	Mail Miscellaneous Communication to Applicant		
07-28-2002	X-Post-Legal Complete Rejection		
07 - 28-2002	Miscellaneous Action with SSP		
05 - 28-2002	Preliminary Amendment		
06-06-2002	X-Pre-Legal Complete Amended Case		
06-06-2002	Date Forwarded to Examiner		131
05-28 - 2002	Response to Election / Restriction Filed		131
05-28-2002	Request for Extension of Time - Granted		•
05-28-2002	Request for Extension of Time - Granted		•
03 - 25-2002	Mail Notice of Informal or Non-Responsive Amendment		- •
03-22-2002	X-Post-Legal Complete Rejection		•
02-07-2002	Case Docketed to Examiner in GAU		
01-23-2002	X-Pre-Legal Complete Amended Case		•
01-23 - 2002	Date Forwarded to Examiner		
01-17-2002	Informal or Non-Responsive Amendment after Examiner Action		↑
01-17-2002	Response to Election / Restriction Filed	62	-₩-
12-17-2001	Mail Restriction Requirement .	63	

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12-15-2001	Regulrement for Restriction / Election	1
06-06-2001	Information Disclosure Statement (IDS) Filed	↑
	Preliminary Amendment	♦
05-17-2001	Information Disclosure Statement (IDS) Filed	*
05-08-2001	Miscellaneous Incoming Letter	^
03-01-2001	Information Disclosure Statement (IDS) Filed	1
11-17-2000	1	1
08-15 - 2000	Information Disclosure Statement (IDS) Filed	4
08-15-2000	Preliminary Amendment	•
07-12 - 2001	Case Docketed to Examiner in GAU	<u>-</u>
06-07-2001	Application Dispatched from OIPE	* •
06-07-2001	Application Is Now Complete	T
10-12-2000	Notice MailedApplication IncompleteFiling Date Assigned	↑
10-11-2000	Correspondence Address Change	^
09-08-2000	IFW Scan & PACR Auto Security Review	f
08-15-2000	Initial Exam Team on	全

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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22315-1450

Date:

June 1, 2005

To:

Technology Center Director

Patent Examining Copps

From:

Joseph J. Rolla

Deputy Commissioner for Patent Examination Policy

Subject:

Acceptance of Certain Non-Compliant Amendments Under 37 CFR 1.121(c)

Effective immediately, the Office will waive certain provisions of 37 CFR 1.121(c)¹ so that the Office may accept amendments that include: (1) the text of canceled claims or not entered claims, and (2) certain variations of status identifiers. Although revised 37 CFR 1.121² has been in effect for over 18 months, the Office is still receiving an unexpectedly high number of non-compliant amendments. The cycle for correcting non-compliant amendments causes extra work for applicants, examiners and the Office's Technical Support Staff, delays in prosecution and increased pendency of applications. Upon review, the Office has determined that certain requirements of 37 CFR 1.121 are not deemed essential in the Image File Wrapper (IFW) environment and that waiver of certain provisions of 37 CFR 1.121(c) will still allow examiners to clearly understand exactly what amendments have been made in IFW applications.

The following amendment submissions are now acceptable:

- Claim listings that include the <u>text of a canceled claim or a not entered claim</u> if the amendment otherwise complies with 37 CFR 1.121, including use of the proper status identifier "canceled" or "not entered," respectively.
- Claim listings that include status identifiers as set forth in the following table if the amendment otherwise complies with 37 CFR 1.121.

Table of status identifiers set forth in 37 CFR 1.121(c) and acceptable alternatives

Status Identifiers Set Forth in 37 CFR 1.121(c)	Acceptable Alternatives
1. Original	Original Claim; and Originally Filed Claim
2. Currently amended	Presently amended; and Currently amended claim
3. Canceled	Canceled without prejudice; Cancel; Cancelled; Canceled herein; Previously cancelled; Canceled claim; and Deleted
4. Withdrawn	Withdrawn from consideration; Withdrawn – new; Withdrawn claim; and Withdrawn-currently amended ³
5. Previously presented	Previously amended; Previously added; Previously submitted; and Previously presented claim
6. New	Newly added; and New claim
7. Not entered	Not entered claim

The Office may also accept other variations of the status identifiers provided in 37 CFR 1:121(c) when the examiner determines that the status of the claims is accurate and clear. The Technical Support Staff (TSS) and examiners should liberally accept variations where the intent of the status identifiers is accurate and clear in view of the record of the application. If the TSS reviews an amendment (other than an after-final amendment) that includes status identifiers not listed in the above table and the amendment otherwise complies with 37 CFR 1.121, the TSS should only mail out a Notice of Non-Compliant Amendment where the status of the amended claim is not accurate and clear in view of the application file record. If the TSS enters an amendment and the examiner thereafter determines that the status of the claims is not accurate and clear in view of the application file record, a Notice of Non-Compliant Amendment must be mailed to the applicant. The examiner may request the TSS to mail out the Notice. Amendments filed after final rejection should continue to be forwarded to the examiner for the usual review of the amendment, including compliance with 37 CFR 1.121. When accepting alternative status identifiers, the examiner is not required to correct the status identifiers using an examiner's amendment, nor shall applicant be notified, and required, to submit a corrective compliant amendment. The examiner does not need to make a statement on the record that the alternative status identifiers have been accepted.

Inquiries concerning this memorandum may be directed to Elizabeth Dougherty or Eugenia Jones, Senior Legal Advisors in the Office of Patent Legal Administration, at (571) 272-7703 or Patent Practice@uspto.gov

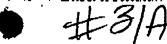
Acceptance of Certain Non-Compliant Amendments Under 37 CFR 1.121(c)

The Office shall waive the provision of 37 CFR 1.121(c)(4)(i) that no claim text shall be presented for any claim with the status of "canceled" or "not entered" and the provisions of 37 CFR 1.121(c) which requires usage of one of the following identifiers: Original, Currently amended, Canceled, Withdrawn, Withdrawn-currently amended, Previously presented, New, and Not entered.

The Office revised the amendment practice set forth in 37 CFR 1.121 in a final rule that became effective July 30, 2003. See Changes to Implement Electronic Maintenance of Official Patent Application Records, 68 Fed. Reg. 38611 (June 30, 2003), 1272 Off. Gaz. Pat. Office 197 (July 29, 2003).

³ 37 CFR 1.121(c) sets forth that "Withdrawn-currently amended" is an acceptable variation of the status identifier "Withdrawn" for a withdrawn claim that is currently amended.





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

MAERTENS et al.

Serial No. 09/638,693

Filed: August 15, 2000

Atty. Ref.: 2752-15

Group: Unassigned

Examiner: Unassigned

For: NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS

THERAPEUTIC AND DIAGNOSTIC AGENTS

November 14, 2000

Assistant Commissioner for Patents Washington, DC 20231

RESPONSE AND AMENDMENT

Sir:

Responsive to the Notice dated October 12, 2000, the applicants respectfully submit the Declaration was filed with the application on August 15, 2000, as evidenced by the attached copy of the undersigned's post card receipt. A further copy of the Declaration is attached for the convenience of the Office. No late fee is believed to be required. Entry of the following amendments is requested.

IN THE CLAIMS:

Amend the claims as follows.

Cancel claims 1-24, without prejudice.

Add the following claims.

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- (ii) removing unbound components,
- (iii) incubating the immunecomplexes formed with heterologous antibodies, which specifically bind to the antibodies present in the sample to be analyzed, with said heterologous antibodies having conjugated to a detectable label under appropriate conditions.
- (iv) detecting the presence of said immunecomplexes visually or by means of densitometry and inferring the HCV serological types present from the observed binding pattern
- 22 A kit for determining the presence of HCV genotypes as defined in any of claims 1 to 5 present in a biological sample liable to contain them, comprising
 - possibly at least one primer composition containing any primer selected from those defined in claim 6 or any other HCV type 2 and/or HCV type 3 and/or HCV type 4 and/or HCV type 5, or universal HCV primers,
 - at least one probe composition according to claim 7, preferably in combination with other polypeptides or peptides from HCV type 1, type 2 or other types of HCV, with said probes being preferentially immobilized on a solid substrate, and more preferentially on one and the same membrane strip.
 - a buffer or components necessary for producing the buffer enabling hybridization reaction between these probes and the possibly amplified products to be carried out.
 - a means for detecting the hybrids resulting from the preceding hybriziation.
 - possibly also including an automated scanning and interpretation device for infering the HCV genotype(s) present in the sample from the observed hybridization pattern
- 23 A kit for determining the presence of HCV antibodies according to any of claims 9 to 15, 17 or 18 present in a biological sample liable to contain them, comprising
 - at least one polypeptide composition according to any of claims 9 to 15, 17 or 18, with said polypeptides being preferentially immobilized on a solid substrate, and more preferentially on one and the same membrane strip.
 - a buffer or components necessary for producing the buffer enabling binding reaction between these polypeptides and the antibodies against HCV present in the biological sample.
 - a means for detecting the immune complexes formed in the preceding binding

SUBSTITUTE SHEET (RULE 26)

PAGE 2/124 * RCVD AT 1130/2006 7:58:07 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-2/0 * DNIS:2738300 * CSID:703 816 4100 * DURATION (mm-ss):06-40

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reaction,

 possibly also including an automated scanning and interpretation device for infering the HCV genotype present in the sample from the observed binding pattern.

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ATTORNEYS AT LAW

11TH FLOOR 901 NORTH GLEBE ROAD ARLINGTON, VIRGINIA 22203 TELEPHONE: (703) 816-4000 FACSIMILE: (703) 816-4100 WRITER'S DIRECT DIAL NUMBER: (703) 816-4091

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TITLE: NEW SEQUENCES OF HEPATITIS C VIRUS
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